HIV INFECTION: CONTINUING EDUCATION FOR HEALTH-CARE PROVIDERS IN 2004

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LEARNING OBJECTIVES:

After reading this article, the health-care provider shall be able to:

a. Discuss the history of the Human Immunodeficiency Virus (HIV);
b. List the modes of transmission;
c. Discuss the diagnosis of HIV;
d. Review the treatment of Acquired Immune Deficiency Syndrome (AIDS);
e. Discuss the confidentiality and legal responsibilities of health-care providers; and
f. Discuss the health-care provider's role.

HISTORY

Since the disease was first detected in June 1981, more than one million Americans have been diagnosed with AIDS and over 501,000 have died. An estimated 5 million people worldwide acquired HIV in 2003, including 4.2 million adults and 700,000 children under 15. During 2003, AIDS caused the deaths of an estimated 3 million people worldwide, including 2.5 million adults and 500,000 children under 15. Aside from the castastrophic loss of life, which has robbed families of loved ones and society of untold talent, the AIDS epidemic has fundamentally changed the fabric of American culture.

It has helped bring men having sex with men into the mainstream, putting these activities and characters on television and in films. It has challenged and stretched religious faith to embrace new ideas about life, death, acceptance, and hope. It has greatly accelerated the government's approval process for all kinds of new drugs. It has challenged all the traditional paradigms about how drug trials are conducted and how drugs are approved.

The dramatic drop in recent years in the number of Americans developing AIDS and dying from the disease appears to be coming to an end. After declining sharply in the mid-1990's, the number of United States AIDS cases and deaths reported each quarter remained stable between mid-1998 and mid-2000. The number of Americans with AIDS rose in 2002 by 2.2%. The increase appears to be related to the increase in risky sexual behaviors, particularly among young men having sex with men. The development of highly active antiretroviral therapy (HAART) to control the infection produced those declines, but the plateau in reported cases and deaths suggests that the treatments have already reached most Americans who know they are infected and who have good access to medical care.

As of December 31, 2003, 4,071 cases of AIDS have been reported in Kentucky, resulting in 1,843 deaths according to the Kentucky Cabinet for Health Services. During this period 3,492 men were infected, making up 86% of the total. Women made up 14% with 550 cases reported. About 68% of the patients were white; 29% were black; and other races made up 3% of the total. State reports show that 57% of the patients were infected during men having sex with men activities, while 13% were infected with contaminated needles during drug use. Heterosexual activity accounted for 12% of the cases, and blood transfusions made up 1%. The North Central Area Development District, which includes Louisville, has reported the largest number of cases (1,865) since 1982. The Bluegrass District during this same time period reported 794 cases, while the Northern Kentucky Area District reported 331 cases. The Buffalo Trace Area Development District in Northeastern Kentucky has reported only 28 cases since 1982. Kentucky ranks 31st among the United States and District of Columbia in cumulative AIDS incidence.

The largest percentage of Kentucky AIDS cases, 46%, are diagnosed in adults in their thirties. The next highest percentage of AIDS cases is among adults in their forties at 25%, followed by adults in their twenties at 18%.

The disproportionate amount of blacks in Kentucky with AIDS is alarming. Twenty-nine percent of the AIDS cases diagnosed statewide as of December 31, 2003 were blacks, though only 7.3% of Kentucky's population is black.

TRANSMISSION

HIV attacks a person's immune system and weakens it, so that it is not able to fight off diseases that enter the body. HIV infection, like many other chronic illnesses, affects nearly every organ system of the body. Someone could be infected with HIV and not know it. That person could have the virus for up to 12 years before he or she starts to get sick and begins showing signs or symptoms of infection. The first stage of AIDS is when you initially get infected. The second stage is when you have the virus without showing any signs of infection. During the third phase you begin to show signs of infection. The fourth stage is when you are considered to have AIDS. This is the final stage of HIV infection. In defining whether an HIV sufferer has developed AIDS, the U.S. Centers for Disease Control (CDC) considers a drop in the blood level of CD4 cells,

the immune system's key infection fighters, to a level below 200 per cubic millimeter of blood.

AIDS is transmitted most frequently by casual sex through the exchange of infected body fluids. This includes vaginal or anal intercourse and may also include oral sex. Other methods of transmission are the sharing of needles between injecting drug users and the administration of blood products contaminated with HIV. The blood-borne transmission of the virus from a mother to her infant is possible as well as transmission through breast feeding. Although the precise mechanisms are unknown, scientists think HIV may be transmitted when maternal blood enters the fetal circulation, or by mucosal exposure to the virus during labor and delivery. The role of the placenta in maternal-fetal transmission is unclear and is the focus of ongoing research. More than four million Americans get pregnant each year, an estimated 8,000 of them HIV-infected. The AZT discovery caused births of HIV-infected babies to drop 43% between 1992 and 1996. Although AZT alone is no longer recommended, AZT should be included as part of an antiretroviral regimen for all HIV-positive pregnant women. Other antiretroviral agents that appear to be safe in pregnancy include didanosine, stavudine, lamivudine and nevirapine. When stavudine and didanosine are taken in combination there may be an increase in the risk of fatal lactic acidosis in pregnant women infected with HIV. Efavirenz is a known teratogen and should be avoided during pregnancy, although it may be less hazardous during the third trimester. Prenatal care that includes HIV counseling and testing and AZT treatment for infected mothers and their children saves lives and resources. Current federal guidelines urge doctors to counsel pregnant women about HIV, but many doctors do not discuss the disease with their patients because it is a burden or they do not think their patients are at risk.

As of December 2002, the CDC was aware of 57 health-care workers in the U.S. who tested negative for HIV infection around the time of exposure, but tested HIV positive within a year after the exposure. Currently there are no federal laws that mandate the national testing of health care professionals for HIV.

The most common exposure to health care workers is through accidental punctures with contaminated needles. An estimated 600,000 health care workers are stuck with needles or other sharp medical instruments in the United States each year. Approximately 384,000 of these injuries occur in American hospitals. More than 60% of those injuries are related to hollow-bore needle sticks. In 1995, the CDC suggested that health care workers who took AZT after an accidental needle stick reduced their risk of contracting the AIDS virus by 79%. Now the CDC is considering whether postexposure prophylaxis (PEP) with drugs such as AZT can effectively abort an infection. Recommendations for HIV PEP include a basic four week regimen of two drugs zidovudine (ZDV) and lamivudine (3TC); lamivudine and stavudine (d4T); or didanosine and stavudine for most HIV exposures and an expanded regimen that includes the addition of a third drug for HIV exposures that pose an increased risk for transmission. The expanded regimen includes the basic regimen plus one of the following: (1) indinavir; (2) nelfinavir; (3) efavirenz; or (4) abacavir. When the source person's virus is known or suspected to be resistant to one or more of the drugs considered for the PEP regimen, the selection of drugs to which the source person's virus is unlikely to be resistant is recommended. Those taking antivirals for PEP should be checked for drug toxicity including a complete blood count, kidney function tests, and liver function tests just prior to and two weeks after the initiation of treatment.

The risk of hepatitis C or HIV from a needle stick is low, under 2%. Do not recommend prophylaxis for hepatitis C exposures, since nothing has been shown to work for hepatitis C post-exposure prophylaxis. The risk of hepatitis B is much higher, around 30%. Recommendations for hepatitis B virus (HBV) postexposure management include initiation of the hepatitis B vaccine series to any susceptible, unvaccinated person who sustains an occupational blood or body fluid exposure. PEP with hepatitis B immune globulin (HBIG) and/or hepatitis B vaccine series should be considered for occupational exposures after evaluation of the hepatitis B surface antigen status of the source and the vaccination and vaccine-response status of the exposed person.

Current CDC guidelines recommend washing needle stick sites and cuts with soap and water, not caustic agents like bleach. Splashes to the nose, mouth or skin should be flushed with water. Eyes should be irrigated with clean water, saline, or sterile irrigants. To track occupational exposures on a nationwide basis, there is a voluntary HIV Postexposure Prophylaxis Registry (888-737-4448) which is completely confidential.

DIAGNOSIS

Diagnosis of HIV is currently based on detecting anti-HIV antibodies. Testing is the only way to determine whether a patient is infected, prior to the appearance of clinical symptoms. The antibody test is typically used because it is cheaper, technologically simpler to perform and interpret, is standardized and widely available. The latest research has shown that early treatment can sometimes delay the onset of the symptomatic phase. Patients recently infected with HIV may have a "window period" of about three to four weeks during which they have viremia and are capable of transmitting the disease, but have not yet developed antibodies. The P24 antigen, the core structural protein of the virus, can be detected about a week before antibodies can be measured. The HIV antibodies may take from six weeks to three months to be detected in the blood. By six months after infection, antibodies are detectable in 95% of patients. The two primary surrogate markers used to follow the course of the infection and response to therapy are CD4 (T4 or T helper) cell count and viral load. T helper cells scour the blood and lymph nodes for cells infected with foreign proteins, a sign of infection. If a T

helper cell comes upon an infected cell, it releases a mist of signaling molecules. Signaling molecules prompt other T cells to copy themselves millions of times and launch an offensive. T cells also can summon B cells, which make antibodies. When HIV flares up and begins multiplying, T helper cells die off. Their numbers drop from roughly 1,500 per microliter of blood to 200 or fewer. When T helper cell counts drop that low, people infected with HIV fall prey to lots of infections that never trouble people who have normal immune systems. CD4 cell count is a useful, but not the ideal surrogate marker. Viral load, measured as HIV RNA in the plasma or serum has been shown to be an important predictor of clinical progression to AIDS. More importantly, these HIV RNA levels respond to therapeutic intervention, making them a useful tool for monitoring therapeutic response. By using viral load as a marker of disease, the risk of AIDS development can be assessed before considerable immune destruction has taken place. Decisions regarding initiation or changes in antiretroviral therapy should be guided by monitoring the laboratory parameters of viral load and CD4 cell count, as well as the clinical condition of the patient. Patients with plasma HIV-1 RNA levels less than 5,000 to 10,000 copies/ml did not appear to progress rapidly. In contrast, as levels increased above 10,000 to 30,000 copies/ml, the risk for progression increased substantially. Based on these observations, physicians recommend therapy for all individuals with plasma HIV-1 RNA levels greater than 20,000 copies/ml, regardless of CD4 cell count.

Enzyme-linked immunosorbent assay (ELISA) is the most common diagnostic test for HIV performed by medical personnel. This test was first developed to screen donated blood so as to eliminate HIV-infected blood from the blood supply. Only later was it used for detecting HIV infection in humans. A negative (nonreactive) result from the ELISA very accurately demonstrates that the blood sample contains no HIV antibodies. When testing people for HIV infection, an initially reactive ELISA should not immediately be accepted as a true positive. A reactive ELISA should be repeated twice. Although the sensitivity of ELISA is extremely high there is still a possibility for false-positive and false-negative results. Some of the most common reasons for a false positive result from an ELISA test are: (1) contamination in a laboratory; (2) false positive reactions have been reported in 19% of people with hemophilia, 13% of alcoholic patients with hepatitis and 4% of hemodialysis patients; (3) pregnancy; (4) history of injection use; and (5) cross-reactivity with other retroviruses. The most widely used confirmatory test is the Western Blot Test. This test show the reactivity of antibodies with HIV-specific proteins that have been separated by electrophoresis. This additional information can help distinguish samples that are true positives from those that are falsely positive on the ELISA. If enough time has elapsed since the last possible exposure to HIV, the ELISA-Western Blot antibody test sequence is extremely accurate in both the negatives and positives. An ELISA plus a confirming test can be done in twenty-four hours, but most laboratories wait a week or longer to accumulate batches of specimens.

The following tests will allow people nationwide to anonymously collect a sample and receive the results usually within seven days.

On May 14, 1996 FDA approved the first HIV test system, called Confide that includes an over-the-counter home use specimen collection kit. Until then, all HIV tests, whether using blood or saliva samples were done under the supervision of a health professional at a medical facility. The Confide system was removed from the US market by its manufacturer in 1997. One approved HIV home collection system being marketed in the United States is the Home Access HIV-1 Test System (also called the Home Access Express HIV-1 Test System). With this home system, the user mails a dried blood sample obtained from a finger prick to a laboratory for analysis. Confidential, highly accurate test results are obtained by telephone with a trained counselor available.

Another test, the OraQuick HIV rapid test (OraSure Technologies, Inc) was approved by FDA in November 2002 and categorized as a waived test under the Clinical Laboratory Improvement Amendments in January 2003. This simple, rapid test provides HIV results in 20 minutes, can be stored at room temperature, requires no special equipment, and can be performed outside clinical settings. HIV-positive test results will require confirmation by Western Blot or immunofluorescence assays.

On June 3, 1996 FDA approved Orasure, the first oral test that appears to be as reliable as the standard blood test to diagnose the HIV virus that causes AIDS. Orasure uses a treated cotton pad to scrape a tissue sample from between the gum and cheek. The mucosal transudate contains large amounts of IgG, the type of antibody used to detect HIV. These proteins can pass through the thin lining of the mouth and gums from blood vessels located close to the surface of the mouth. The collection pad, which looks like an ordinary cotton swab, encourages the flow of these proteins, which are then drawn into the pad. The test is an alternative for people at risk for HIV but who shun blood tests.

On August 6, 1996 FDA approved the first HIV test that uses urine samples. All previously approved HIV tests used either blood or oral fluid samples. The new urine-based test detects the presence of antibodies to HIV-1, using an enzyme linked immunosorbent assay (ELISA) method. The test can be ordered only by a physician. It is marketed under the names of Calypte HIV-1 urine EIA and Seradyn Sentinel HIV-1 urine EIA. Patients with a positive test should have a blood sample drawn for confirmation.

The FDA on June 3, 1996 approved a new test to predict the risk of HIV disease progression in patients

by measuring virus levels in blood. The test is the first HIV-1 test approved using polymerase chain reaction (PCR) technology. By amplifying genetic material from HIV-1, the virus that causes most AIDS cases in the United States can measure the amount of virus in the blood more precisely than other approved technologies. The newly approved PCR test is not labeled for use as a screening test for HIV or as a diagnostic test to confirm HIV infection. The test is called the Amplicor HIV-1 Monitor Test.

TREATMENT

At the time of publication, twenty antiretroviral drugs had been approved by the Food and Drug Administration. Antiretroviral therapy for treating patients with HIV infection is ever changing as new agents are approved by FDA. Our understanding of the basic pathophysiology and immunology of HIV infection continues to evolve on an almost daily basis, and drug development occurs at a rapid pace. Since 1990, FDA has averaged one new antiretroviral agent approval per year; several years have seen the approval of two or three new antiretrovirals. Currently five classes of agents are available--nucleoSIDE analog reverse transcriptase inhibitors (NRTIs); protease inhibitors (PIs); nonnucleoside reverse transcriptase inhibitors (NNRTIs); nucleoTIDE analog reverse transcriptase inhibitors; and fusion inhibitors (FIs). Each class inhibits replication of HIV, although at different points in the replication process, giving them synergistic action in combination regimens and delaying the emergence of resistant HIV strains. As a result, therapy now focuses on combinations of antiretroviral agents to reduce viral load (viral burden) and increase CD4 counts. The latest HIV guidelines are the following: HIV therapy is started right away for all symptomatic patients and for patients who have turned HIV positive in the last six months. The biggest change from previous guidelines is to delay therapy for asymptomatic patients who have been HIV positive for longer than six months. For these patients, physicians may want to consider delaying antiretroviral therapy until CD4 counts drop below 350 instead of 500, or viral load is more than 55,000 instead of 20,000. The combination referred to by some as "drug cocktails" are helping AIDS patients lead healthier and longer lives. Two NRTIs (lamivudine, zidovudine or stavudine), plus one NNRTI (efavirenz) are being prescribed more and more by physicians as initial treatment. Other cocktail combinations consist of a protease inhibitor and two nucleoside analog reverse transcriptase inhibitors, mainly zidovudine plus didanosine, zalcitabine or lamivudine, or stavudine plus either didanosine or lamivudine, along with a protease inhibitor, either indinavir, ritonavir or nelfinavir. The drug cocktails reduce the HIV virus in a patient's blood to undetectable low levels, but unfortunately it is not a cure. Previous research suggests that when administered in combination with antiretroviral drugs, hydroxyurea (Hydrea) produces consistent, sustained viral suppression and restores immune functioning in patients infected with HIV. This combination is not recommended due to lack of sufficient data. Also according to medical reports, testosterone injections are being administered to HIV positive men to help relieve symptoms of fatigue. Testosterone deficiency is the most common hormonal abnormality in men with HIV infection.

Zidovudine (AZT; Retrovir) was approved in March of 1987 and is manufactured by Glaxo-Wellcome. Didanosine (ddI; Videx) was approved in October of 1991 and is manufactured by Bristol-Myers Squibb. Zalcitabine (ddC; Hivid), manufactured by Hoffmann-La Roche, was approved in August of 1992. Stavudine (d4T; Zerit), manufactured by Bristol-Myers Squibb, was approved in July of 1994. Another antiviral medication for HIV is lamivudine (3TC; Epivir) and is manufactured by Glaxo-Wellcome. Abacavir (Ziagen) was approved on December 18, 1998 and is manufactured by Glaxo-Wellcome. Emtricitabine (Emtriva) was approved on July 2, 2003 and is manufactured by Gilead Sciences. These drugs are similar to one another in that they prevent replication of HIV by inhibiting an enzyme called reverse transcriptase. While the drugs do not kill the virus, they delay the progression of the disease, helping the patient retain their immune system function and minimizing opportunistic infections that could be fatal.

Retrovir, Videx, Hivid, Zerit, Epivir, Ziagen and Emtriva are all classified as nucleoside analogues. Treatment usually begins when there is a change in the CD4 (T4 or T helper) cell count The absolute number of CD4 cells is one measure of therapeutic response, but this test does not reliably predict clinical outcomes. CD4 cell counts reflect the strength of the immune system and are generally 800 to 1,000 cells/mm^3 or higher in healthy adults. The number of CD4 cells in the body gradually declines in an HIV-infected person. In previous years, physicians started treatment when an AIDS patient's CD4 count fell below 500. CD4 cells act as the ON switch for part of the immune system, so as the number of CD4 cells drops, damage to the immune system progresses. Over time, individuals become increasingly susceptible to diseases caused by organisms that are usually kept in control by a healthy immune system. All NRTIs can cause lactic acidosis, a fatal metabolic disturbance that causes an abnormal buildup of lactic acid with symptoms that may include an enlarged liver.

Retrovir is the preferred drug for initial therapy and is initiated when CD4 levels decrease to approximately 500 cells/mm^3. The recommended adult dose is 500-600mg daily and appears to be well tolerated at this dosage range. The FDA approved Retrovir for use in preventing the transmission of HIV from HIV-infected pregnant women to their babies. Therapy should begin between 14 and 34 weeks after conception. The newborn should begin oral doses of Retrovir within 24 hours after birth and for six weeks thereafter. The dose is generally 2mg/kg every six hours for the newborn. Patients may experience severe side effects while

taking Retrovir. The two most prominent side effects are anemia and granulocytopenia. Frequent blood counts are recommended for patients taking this drug. Other side effects frequently seen with Retrovir are fever, rash, nausea, headache, loss of appetite, insomnia and diarrhea. Retrovir comes in 100mg capsules and may be taken with food. However, administration with a meal high in fat content should be avoided.

Patients who cannot tolerate Retrovir may be switched to Videx. Videx is available in 25, 50, 100 and 150mg tablets. Videx is usually given twice daily on an empty stomach, at least 30 minutes before or two hours after eating, and is dosed on the basis of the patients weight. The most serious side effects are pancreatitis, which may be life threatening, and peripheral neuropathy, which occurs in 5% to 12% of patients. Pharmacists should instruct patients taking Videx that at the first sign of pain, numbness and tingling in the extremities, usually the lower legs and feet, they should discontinue the medication. Peripheral neuropathy is dose-related. Videx EC is a new enteric-coated didanosine capsule. It should be swallowed whole, instead of being chewed or dispersed in water. The usual dose is once daily on an empty stomach. The enteric coating protects the drug from being degraded in the stomach, so it does not require a buffer like the original tablet.

Hivid may be used alone or in combination with Retrovir. It is used in combination with Retrovir to increase the antiviral effects of Retrovir in adult patients. Studies show that this combination may increase the CD4 count. Hivid is supplied in 0.375 and 0.75mg tablets and is usually dosed three times daily with plenty of water. The major side effect is peripheral neuropathy, which occurs in 17 to 31% of patients. Stomatitis, esophageal ulcerations, headache, and nausea are also common side effects.

Zerit is a second-line option for patients unable to take Retrovir or Videx because of intolerance, treatment failure, or contraindication. Zerit comes in 15, 20, 30 and 40mg capsules. The recommended starting dose is 40mg twice daily for patients weighing 60kg or more. The most common side effect is peripheral neuropathy, which was reported in 15% to 21% of patients and is dose-dependent.

Epivir may be used in combination with Retrovir as first line treatment of AIDS and HIV infection. Trial studies show that patients treated with the 3TC/AZT combination sustained higher increases of CD4 cells than patients on the other three regimens. The recommended starting dose of 3TC is 150 to 300mg twice daily. Some side effects with 3TC are nausea, diarrhea, anemia, neutropenia, pancreatitis and neuropathy.

FDA approved abacavir/ABC (Ziagen) on December 18, 1998 for the treatment of HIV-1 infection in adults and children. The recommended oral dose of Ziagen for adults is 300mg twice daily, with or without food and in combination with other antiretroviral agents. Adolescent and pediatric patients aged three months to sixteen years should receive 8mg/kg twice daily (up to a maximum of 300mg twice daily). The product is supplied as 300mg tablets and as a strawberry banana-flavored oral solution containing 20mg/ml of abacavir. A potentially fatal hypersensitivity or allergic reaction has been associated with the use of Ziagen in at least 3-5% of patients. Symptoms of this reaction may include skin rash, fever, nausea, abdominal pain and severe tiredness. A written list of the hypersensitivity symptoms is printed on a warning card and should be provided along with a Medication Guide to patients by pharmacists with each new prescription and refill. Patients should be instructed to carry this card with them at all times. Anyone who experiences a hypersensitivity reaction must stop taking the medicine and call his/her health-care provider immediately. Ziagen should not be taken again after a reaction occurs because more severe symptoms will arise within hours and may include life-threatening low blood pressure or death. Additional side effects of Ziagen include nausea, vomiting, fatigue, headache, diarrhea and loss of appetite.

Emtriva, the seventh NRTI to treat HIV is manufactured by Gilead Sciences. Emtriva prevents HIV from entering the nucleus of healthy T-cells. This prevents the cells from producing new virus and decreases the amount of virus in the body. Emtriva must be used in combination with other drugs, including another NRTI and at least one PI or NNRTI. The prescribed dose of Emtriva is one 200mg capsule once a day with or without food and is an analog of cytosine. In clinical trials, the most common adverse effect was hyperpigmentation of the soles of the feet and palms of the hands. Emtriva also appears to be active against the hepatitis B virus (HBV), a virus that can cause liver damage in a small number of people infected by it. Like other NRTIs, the drug carries a warning for the possibility of lactic acidosis with hepatic steatosis.

In December of 1995, FDA approved the first protease inhibitor (PIs), adding a new class of therapy for the treatment of advanced HIV infection. The protease inhibitors are the most potent antiviral agents available so far. They slow the growth of the AIDS virus by interfering with an enzyme that is crucial to viral replication. Because PIs act synergistically with the NRTIs and immunologic resistance develops rapidly when PIs are used alone, you may only see them prescribed in combination with NRTIs. The protease inhibitors must be taken religiously to be effective. Missing a dose or two can cause the level of the drug in the bloodstream to fall and allow the AIDS virus in the patient's body to mutate. With each mutation, the virus becomes more drug resistant. Over-the-counter antidiarrheals are generally effective in managing GI discomfort and nausea associated with protease inhibitors.

Saquinavir is manufactured by Roche Laboratories under the trade name Invirase. It is well tolerated both alone and in combination with zidovudine and zalcitabine. Nausea, abdominal pain, and diarrhea are a few side effects seen with this drug. Serum concentrations of saquinavir may be lowered with the use of either

rifabutin or rifampin. There is new evidence that garlic supplements can decrease levels of Invirase. A lot of HIV patients are trying garlic because of its reported antiviral and immunostimulant effects. Currently, there is no proof that garlic is helpful, so you may wish to advise your patients that decreased HIV drug levels of Invirase can cause therapeutic failure leading to increase viral resistance.

On November 7, 1997 FDA approved a new formulation of Invirase. Fortovase (saquinavir) comes in a soft gelatin capsule that delivers more drug through the body than its predecessor. Fortovase also stays in the body at increased levels, thus improving treatment. A controlled clinical study showed that at sixteen weeks of treatment, twice as many patients who received Fortovase had undetectable virus levels in the blood compared to those who received Invirase. The most common adverse effects are gastrointestinal, including diarrhea, nausea, and abdominal discomfort. Fortovase is taken in 1200mg doses, three times a day.

In March of 1996, FDA approved two new protease inhibitors. Ritonavir, the second drug approved in this class may be used alone or in combination with nucleoside analogues in patients with advanced HIV disease. Ritonavir (Norvir), manufactured by Abbott Laboratories, not only improves laboratory markers, such as CD4 counts and viral load, but it can reduce disease progression and mortality in patients with advanced HIV disease. Side effects associated with ritonavir treatment includes diarrhea, nausea, vomiting, liver inflammation, elevation of lipid levels, and taste disturbance. Ritonavir's use may be limited because of its numerous drug interactions (especially hypnotic agents), and side effects and should not be used in patients with liver disease, hepatitis, or hemophilia. Abbott was experiencing difficulty manufacturing Norvir in capsule form because of solubility problems. Norvir 100mg capsules are now available in a new soft gelatin formulation. Pharmacists should remember to store the gelcaps in the refrigerator before dispensing. Pharmacists should also instruct their patients that they can keep the gelcaps out of the refrigerator for up to thirty days as long as the temperature does not exceed 77 degrees F. Advise patients to take Norvir with a meal to increase absorption. There are now reports of serotonin syndrome in HIV patients taking Prozac and Norvir. Norvir is a potent inhibitor of cytochrome P450 enzymes and can slow the metabolism of Prozac. This could lead to confusion, muscle spasms, tremors, fever, abdominal pain and anxiety. Keep in mind that Norvir may also increase the risk of serotonin syndrome when used along with other selective serotonin reuptake inhibitors (SSRIs) or high doses of tricyclic antidepressants.

Indinavir, the third protease inhibitor to treat HIV is manufactured by Merck & Co., under the trade name Crixivan. FDA approved this drug just 42 days after receiving its application for its marketing. Like ritonavir, it too improves laboratory markers such as increased CD4 counts and decreased viral loads in patients. Nausea, abdominal pain and frequent increases in bile production are some of the adverse reactions to the drug. It is recommended that the patient consume large amounts of water (one & one-half liters daily) to reduce the incidence of kidney stones while taking the drug. Crixivan may be linked to symptomatic urinary tract disease and transient kidney dysfunction as a result of crystal formulation in the urine. Patients may develop urological symptoms, including flank pain and painful urination.

Another protease inhibitor is nelfinavir. It is manufactured by Agouron and marketed under the name of Viracept. Patients commonly receive 750mg three times a day with food. Antiviral activity of nelfinavir may be increased by indinavir and ritonavir. Viracept should not be administered concurrently with cisapride, triazolam, midazolam, or rifampin. The most common side effects with Viracept are diarrhea, nausea, and headaches.

The fifth protease inhibitor approved by the FDA is agenerase (Amprenavir), manufactured by Glaxo-Wellcome. It was granted accelerated approval in April 1999 for use in combination with other antiretroviral agents for the treatment of HIV-1 infection. The recommended dose for adults and adolescents (13 to 16 years of age) is 1200mg (eight 150mg capsules) twice daily. The recommended dose for pediatric patients between four and twelve years of age is 20mg/kg twice daily to a maximum of 2400mg. It is available in a 50mg capsule and liquid for children, but do not substitute the same dose of liquid for the capsule because the liquid form is 14% less bioavailable. Caution patients not to take supplemental vitamin E since the vitamin E content of agenerase capsules and oral solution exceeds the Reference Daily Intake (RDI). Advise patients to contact their doctor if they develop nausea, vomiting, diarrhea, rash, or numbness around the mouth. Like the other PIs, agenerase inhibits cytochrome P450 enzymes. Do not coadminister agenerase with rifampin, triazolam, bepridil, cisapride, midazolam, ergotamine, or dihydroergotamine.

FDA, on September 15, 2000 issued an accelerated approval for Kaletra, a protease inhibitor for adults and children greater than six months of age with HIV. Manufactured by Abbott Laboratories, Kaletra is a combination of lopinavir and ritonavir in a ratio of 4:1. Lopinavir's antiviral properties are combined with a low dose of ritonavir that inhibits lopinavir's metabolism, resulting in higher and more sustained drug levels. Patients take Kaletra in combination with other anti-HIV drugs. The usual dose for adults is 3 capsules or 5.0mls twice daily with food to increase absorption into the blood stream. The dose for children six months to 12 years is based on weight and is also given twice daily with food. Side effects associated with Kaletra are diarrhea, fatigue, headache, and nausea. Kaletra also produces increases in blood lipid levels and glucose levels. In addition, infrequent cases of pancreatitis have been observed among patients receiving antiretroviral regimens

that included Kaletra. Coadministration of Kaletra with drugs that are highly dependent on CYP3A or CYP2D6 for clearance and for which elevated plasma concentrations are associated with serious and/or life-threatening events is contraindicated. Encourage patients to report concomitant use of OTC medications, including herbal products such as St. John's wort. Watch for potentially serious interactions with lovastatin, triazolam, rifampin, oral contraceptives, and sildenafil. Patients do not need to refrigerate Kaletra if it is used within two months and stored below 77 degrees F, but pharmacies should store Kaletra at 36 to 46 degrees F until dispensed.

On June 20, 2003, the FDA approved the seventh protease inhibitor, Reyataz (atazanavir), to be used in combination with other anti-retroviral agents. Reyataz, manufactured by Bristol-Myers Squibb only needs to be taken once daily with food and has a low pill burden (two pills each day). The most common laboratory abnormality observed with the use of Reyataz is hyperbilirubinemia. This abnormality resulted in the clinical adverse reaction of jaundice (yellowing of the skin) or scleral icterus (yellowing of the eyes) in 15-24% of subjects taking Reyataz. This abnormality was shown to be reversible upon discontinuation of the drug. Reyataz appears to have minimal impact on lipid parameters such as triglycerides and cholesterol.

The FDA is currently warning pharmacists and patients that the new protease inhibitors might increase lipid levels and blood sugar levels which might worsen or lead to new diabetes. Advise patients to watch for signs of hyperglycemia, such as weight loss, fatigue, increased thirst and increased urination to name a few. Physicians are prescribing metformin (Glucophage) 850mg daily for treating the metabolic complications of HIV treatment. Adding Glucophage appears to lower glucose and lipid levels in some patients. Patients taking PIs concurrently with Viagra should be told that PI's slow Viagra metabolism thus leading to significantly higher and more prolonged levels.

On September 26, 1997, FDA approved a combination of AZT (zidovudine) and 3TC (lamivudine) for treating AIDS and HIV infection. Combining these two drugs, which are commonly prescribed with one another, into one tablet could decrease the number of pills patients with HIV have to take daily. Combivir is manufactured and marketed by Glaxo-Wellcome and can be given twice a day instead of up to eight tablets as in the AZT-3TC regimen.

In June of 1996, FDA approved the first nonnucleoside reverse transcriptase inhibitor (NNRTI). These drugs interfere with HIV replication in a similar manner to the older nucleoside analogues. Nevirapine (Viramune) is only recommended for use in combination with at least one other antiretroviral agent. A pediatric formulation of Viramune is approved for the treatment of infants and children with HIV. It was the first NNRTI approved for infants with HIV and is also being prescribed for HIV-positive pregnant women. Nevirapine's most common adverse reactions are severe rash, fever, nausea, headaches and abnormal liver function tests.

Delavirdine is the second NNRTI approved by FDA. It is manufactured by Pharmacia & Upjohn and is marketed under the brand name, Rescriptor. It also must be used in combination with other antiretroviral drugs due to risk of resistance developing. Rescriptor is usually given 400mg three times daily and absorption may be reduced by antacids. The most common side effect is a rash, which in rare cases has been reported to be severe or life threatening. Delavirdine, like the protease inhibitors, is an inhibitor of CYP 3A4, while nevirapine is an inducer.

On September 18, 1998, FDA approved efavirenz, manufactured by Dupont Pharmaceuticals and marketed under the name Sustiva. Sustiva is the third NNRTI approved by FDA to treat HIV and AIDS in children and adults. Efavirenz, in combination with other antiretroviral agents, was approved to treat HIV-1 infection after 24-week studies showed it to be effective in suppressing HIV. Drug labeling recommends that patients take 600mg of efavirenz once daily in combination with a protease inhibitor and/or nucleoside analogue reverse transcriptase inhibitor. Although the drug may be taken with or without food, the label suggests that patients avoid high-fat meals. Sustiva appears to be as potent as a protease inhibitor when combined with the nucleoside inhibitors, Retrovir and Epivir. Studies have shown Sustiva penetrates into the cerebrospinal fluid, a common viral sanctuary. Adverse reactions include dizziness, drowsiness and impaired concentration. Abnormal dreams have been reported in more than half of the patients treated with efavirenz. Suggest to patients they may want to take Sustiva between 6:00 pm and 8:00 pm to avoid some of the CNS effects. The CNS effects usually disappear after 2 to 4 weeks. A good rule of thumb is for patients to take Sustiva 12 hours before they need to be alert the next day. Approximately 27% of adult patients and 40% of children experienced a skin rash during clinical trials. The following drugs should not be coadministered with Sustiva: midazolam, triazolam, cisapride, and ergot derivatives.

On November 15, 2000, FDA approved Trizivir for the treatment of HIV in adults and adolescents. Each dose of Trizivir is a fixed-dose combination of Ziagen, Retrovir and Epivir. Trizivir is manufactured by Glaxo-Wellcome and is not recommended for treatment in adults or adolescents who weigh less than 40 kilograms because it is a fixed-dose tablet. The recommended dose is one tablet twice a day. Health-care providers need to warn their patients of the adverse reactions to each of the medications, especially the hypersensitivity caused by abacavir.

Gilead Sciences received FDA approval in October 2001 for its new antiretroviral agent Viread (tenofovir disoproxil fumarate) for the treatment of HIV infection when taken in combination with other

antiretroviral agents. Viread is the first nucleoTIDE analogue reverse transcriptase inhibitor approved for the treatment of HIV. The drug is dosed as one 300mg tablet once daily with a meal. Viread works by blocking reverse transcriptase. As a nucleotide, Viread remains in cells for long periods of time, thus allowing for once daily dosing. Viread is predominantly renally excreted and should not be administered to patients with creatinine clearance of less than 60ml/min. Mothers receiving Viread should not breast feed. Viread can increase didanosine levels. Advise patients to take Viread two hours before or one hour after didanosine. Viread also appears to be active against the hepatitis B virus.

In March of 2003, FDA approved the first fusion inhibitor, enfuvirtide (Fuzeon), adding a new class of therapy for HIV-positive people who have taken (and failed) other antiviral agents in the past and are unable to keep their viral loads undetectable. Fusion inhibitors bind to viral particles and prevent adhension to CD4 cells. Unlike other antiretrovirals, enfuvirtide is administered twice daily as a subcutaneous injection. The major adverse effect associated with enfuvirtide is injection-site reaction, which occurs in nearly all patients (98%). Fuzeon is manufactured by Hoffmann-LaRoche.

Opportunistic infections (OP's) are the most frequent cause of death in people with AIDS. Once HIV infects or kills a significant number of CD4 cells, the person's immune system is weakened to the point that it cannot fight off normal infections and these result in severe illnesses. Infections due to the opportunistic pathogens in patients with AIDS may be managed successfully when appropriate therapy is promptly given.

Pneumocystis carinii pneumonia (PCP) represents the most common infectious complication. It occurs in up to 85% of all patients with AIDS. PCP usually starts with a persistent low grade fever, nonproductive cough, and shortness of breath. The therapeutic choice depends on the severity of the pulmonary infection. Primary therapy for acute PCP is trimethoprim and sulfamethoxazole (TMP-SMZ) because of its proven efficacy. Alternate regimens include pentamidine and dapsone.

Cerebral toxoplasmosis occurs in approximately 10% to 40% of AIDS patients with reactive serologies to *toxoplasma gondii*. The common presenting symptoms are impaired cognitive abilities, headache, fever, and focal neurologic signs. Pyrimethamine and sulfadiazine are the preferred drugs for toxoplasmosis therapy.

Mycobacterium avium complex (MAC) is a group of slow growing mycobacteria commonly found in food and water. MAC causes fever, night sweats, diarrhea, anorexia, abdominal pain, and wasting. Clarithromycin or azithromycin are preferred prophylactic agents. If these agents cannot be tolerated, rifabutin is an alternative prophylactic choice.

Cryptococcus neoformans is present worldwide in bird feces, soil, and farm produce. It may infect various sites, but most commonly presents as meningitis. Fever, headache, neck stiffness, and altered mental status are often reported. The standard treatment of cryptococcal meningitis in HIV-infected patients is amphotericin B with adjunctive flucytosine.

Mucosal candidiasis is common in HIV-infected patients. The clinical presentation of oral candidiasis is a creamy white curdlike lesion occurring in patches along the mucosal surface. It can be treated with clotrimazole trouches, nystatin or ketoconazole.

Cytomegalovirus (CMV) is a member of the herpes family that can infect several sites in immunocompromised patients. Retinitis, colitis, and esophagitis are the most common clinical manifestations. CMV retinitis results in irreversible visual losses. Foscarnet and intravenous ganciclovir are the mainstays of therapy. Patients with AIDS who experience CMV retinitis have a new treatment option with fomivirsen sodium (Vitravene). Vitravene is manufactured by Isis Pharmaceuticals and Ciba Vision. Adverse reactions listed were ocular inflammation (uveitis), including iritis and vitreitis.

Tuberculosis (TB) is on the rise in the United States and this may be problematic for HIV-infected patients. Since HIV attacks the immune system, patients infected with HIV are more susceptible to developing active TB, caused by the bacterium, *mycobacterium tuberculosis*. Treatment centers around Rifamate, Myambutol, streptomycin sulfate, pyrazinamide, and Priftin. New guidelines from the CDC recommend screening for TB in all HIV-infected people. The use of rifampin, which is commonly prescribed for TB, is contraindicated with PIs and NNRTIs. Early diagnosis and effective treatment of TB among HIV-infected patients is critical to cure tuberculosis, minimize the negative effects of TB on the course of HIV, and interrupt the cycle of transmission to others.

Kaposi's sarcoma (KS) is a malignant tumor usually involving the skin and commonly encountered in HIV-infected patients. The most common manifestations of KS are cutaneous lesions consisting of bluish-red or purple nodules made up of vascular tissue. Early lesions may start on the feet or ankles, and spread to the arms and hands. Until recently, only parenterally administered therapies had been approved for the treatment of KS. Alitretinoin (Panretin) gel 0.1% from Ligand Pharmaceuticals is the first topical therapy indicated for AIDS-related KS. Initially, it should be applied twice daily to cutaneous lesions, but may be increased to three or four times daily. Adverse reactions include erythema, pain, pruritus, and vesiculation.

CONFIDENTIALITY AND LEGAL RESPONSIBILITY OF HEALTH-CARE PROVIDERS

Health-care providers must use professional discretion to maintain confidentiality for HIV-infected patients. The Civil Rights Act of 1964, Rehabilitation Act of 1973, and Americans with Disabilities Act of 1990 all protect patients with AIDS or related conditions from discrimination. For example, if a pharmacist refuses drug therapy to a HIV-infected patient who is a Medicare and/or Medicaid recipient, he/she could be held liable under the Americans with Disabilities Act.

As an integral member of the health care team, the pharmacist has the legal and ethical obligation to dispense medications, and offer counseling and information to the patient without discrimination. Health-care providers may not use the diagnosis of HIV infection or AIDS to discriminate against these persons from employment, who are otherwise qualified for the position. The ADA also provides protection for potential or present employees infected with HIV.

The Occupational Safety and Health Administration (OSHA) has amended part 1910 of title 29 of the code of Federal Regulations to require employers of pharmacists and podiatrists to provide a safe work environment. Part of the regulation mandates the use of universal precautions to reduce the risk of occupational HIV transmission. If health-care providers come into contact with blood, saliva, body tissues, or other potentially infectious materials they should adhere to the following:

a. Wash hands with an antimicrobial soap before and after putting on gloves;
b. Wear protective equipment such as latex gloves, masks, and goggles;
c. Do not recap used needles or place covers on other used sharp instruments such as razors;
d. Dispose of needles or other sharp instruments properly; and
e. Place all contaminated waste in a leak-proof airtight container that has appropriate signage.

Kentucky law requires that permission must be obtained prior to HIV testing on any individual. The only exception to the rule is when testing is necessary to diagnose an emergency situation in which the person being tested cannot give permission due to his/her medical condition. Every county health department in the Commonwealth must offer free anonymous and confidential HIV testing to persons upon request.

The Department for Public Health has amended 902 KAR 2:020 requiring any health professional licensed under KRS 311 through 314, any health facility licensed under KRS 216B, and any laboratories licensed under KRS 333 to notify the local health department in which the patient resides, or the Department for Public Health within five business days upon arriving of a probable diagnosis of diseases and conditions of public health importance which would include HIV-infected patients. A log shall be maintained by the physicians, health facilities, and laboratories with the name of the person tested HIV positive and the unique code assigned to the HIV positive person. Reports for persons with HIV infection without a diagnosis of AIDS shall be identified by an unique code consisting of the persons: Last & first initials, date of birth, and last four digits of his/her social security number. Reports of AIDS cases shall include the patient's full name, address, the date of onset of the illness and any opportunistic infections diagnosed as well as any other information required by this regulation.

THE HEALTH-CARE PROVIDERS ROLE

As a health-care provider, the pharmacist can be a valuable resource for the HIV-infected patient. Pharmacists have a responsibility to provide pharmaceutical care to these patients and can expand their role through collaborative drug therapy management. 201 KAR 2:220 allows pharmacists to enter into agreements with an individual practitioner to select appropriate medication therapies for patients who have a confirmed diagnosis and adjust these therapies on the basis of patients' responses. Patients should expect pharmacists to provide up-to-date information, guidance and counseling concerning drug therapy. More importantly, pharmacists can provide education to the community about the risks of contracting the disease and the prevention of HIV transmission. Pharmacists are likely to be seen more often by patients than any other health-care provider in the early stages of the disease. This situation places pharmacists in an excellent position to provide counseling to HIV-infected patients. To be effective as counselors, pharmacists must be able to manage the sometimes unique and uncomfortable situations associated with this disease. They must be able to address patients' perceptions of their individual needs and be able to discuss issues such as adverse drug effects, drug interactions and mechanisms of action of drugs. AIDS is perceived in many different ways and its perception is influenced by a great deal of factors within the patient and the society in which he/she lives. In our society today, AIDS is often perceived as a retribution for unacceptable behavior--and this attitude must change.

The pharmacist may see the AIDS patient more frequently than his/her doctors do, so the pharmacist should be alert to personality or behavioral changes in the patient. The patient might exhibit the following behavioral changes: (1) depression; (2) confusion; (3) denial; (4) guilt; and (5) anger. Pharmacists not only have to help the patient confront these changes that arise, but often serve as a vital referral source by maintaining a support list of names, addresses and phone numbers of medical personnel and organizations that can assist the patient and his/her family. With AIDS, health-care providers have to work together because the disease is just

too complicated to go at it alone.

The health-care providers role in AIDS patient care is much more likely to grow than to diminish in the coming years as more AIDS patients live longer and receive treatment that is more consistent with chronic care. Pharmacists should educate their patients on the need to follow a given drug regimen and the risks they will face if they don't comply--particularly the danger of developing resistance. The first two weeks with some of the HIV/AIDS drugs are extremely difficult because of the adverse reactions. Today, many AIDS patients are doing something they only could have dreamt of previously--they are planning for the future. Pharmacists can assist HIV patients by educating them about the importance of consistency with medication schedules. The critical link between the efficacy of HIV drugs and their effectiveness is clearly adherence. Because many HIV-infected patients feel disconnected from the community, compassion on the part of the pharmacist can forge a strong bond with the patient and perhaps enhance patient adherence to antiretroviral treatment. Adherence is a problem among HIV patients because they skip pills to avoid side effects, find the instructions hard to follow, sleep through doses, dislike the interruptions in their lifestyles, or just plain forget to carry their pills with them. While there are many ways to measure adherence, most of us still use patient self-reporting as an adherence indicator. So the initial steps in the development of a treatment adherence strategy is to question patients about treatment adherence in ways that allow them to give an honest assessment instead telling us what they think we want to hear. Causes of nonadherence are multifactorial and differ greatly from patient to patient. The principal factors associated with nonadherence to antiretroviral therapies appear to be patient-related and include mental illness, unstable housing, active substance abuse, and major life crises.

A increased effort is aimed at getting HIV patients to take at least 95% of their antiretroviral medications on time. This means most patients can not miss more than one dose per week. When patients take only 90% of their antiretroviral medications on time, the rate of drug failure or resistance jumps to over 50%. Under 70% compliance there is a 80% failure rate. So talk to your patients on the importance of adhering to HIV drug regimens.

Pharmacists should be on the look out for sound alike names for the drugs that treat HIV/AIDS patients. Medication errors have been reported on nevirapine (Viramune) and nelfinavir (Viracept); zidovudine (Retrovir) and ritonavir (Norvir); and lamivudine (Epivir) and lamotrigine (Lamictal). Pharmacists may wish to place warning labels on the individual packages and shelves where the drugs are stored and add warnings in the computer to alert the pharmacist filling prescription orders for these drugs. In addition, health care providers should avoid using abbreviations or symbols when prescribing, dispensing or transcribing.

The following are guidelines for safer sex and should be stressed when discussing the risks of contacting the disease: (a) avoid having sex with a person suspected of having AIDS; (b) latex condoms with a spermicidal gel should always be used prior to any sexual contact; (c) avoid any exchange of body fluids: (d) avoid oral-genital contact; (e) avoid having sex with an injecting drug user; (f) abstinence and long term mutually monogamous relationships are two effective means to prevent infection; (g) casual touching or shaking hands with someone infected with HIV does not spread the infection; (h) due to the concentration of virus in ejaculate, the receptive partner is at higher risk; (i) partners can become infected after a single episode of heterosexual vaginal intercourse with an infected partner; and (j) female condoms are currently available to protect the lining of the vagina and reduce the risk of transmission.

If syringes/needles are to be shared, there is not a 100% effective way of cleaning them. The following cleaning procedure can be offered to the patient if they plan to share syringes/needles:

* Dip the syringe/needle in pure bleach and draw the bleach up into the syringe;
* Allow the syringe to remain in the bleach for at least 30 seconds;
* Lightly shake the syringe against a hard object to dislodge any blood particles;
* Release the bleach into a container that will be properly discarded; and
* Repeat the process using water to flush out any residual bleach.

HIV INFECTION: CONTINUING EDUCATION FOR HEALTH-CARE PROVIDERS IN 2004

CHS # 0306-1045-S

To obtain 2.0 hours (0.2 CEU), please answer the following questions and circle your answers clearly on the answer sheet. Select the most correct answer.

1. The risk for the health care worker of contracting hepatitis B through accidental punctures with contaminated needles is:

   a. Less than 2%
   b. 10%
   c. 30%
   d. None of the above

2. The latest nucleoside analogue approved by FDA is:

   a. Epivir
   b. Fuzeon
   c. Emtriva
   d. Reyataz

3. The cell that suffers the most damage in HIV infection is the:

   a. T helper cell
   b. Plama cell
   c. Macrophage
   d. Red blood cell

4. Emtriva maybe taken alone or used in combination with other antiviral agents:

   a. True
   b. False

5. Which of the following drugs is administered by subcutaneous injection?

   a. Ziagen
   b. Fuzeon
   c. Norvir
   d. Kaletra

6. Which of the following HIV tests was approved in 2002 by FDA?

   a. Orasure
   b. OraQuick
   c. Confide
   d. Home Access

7. The most common laboratory abnormality observed with the use of Reyataz is?

   a. Hyperpigmentation
   b. Hyperlipidemia
   c. Hyperbilirubinemia
   d. Hyperglycemia

8. Which of the following has a once a day dosing guideline?

   a. Ziagen
   b. Kaletra
   c. Reyataz
   d. All of the above

9. Trizivir is a fixed-dose combination of Ziagen, Retrovir, and Epivir.

   a. True
   b. False

10. What area in Kentucky has reported the largest number of AIDS since 1982?

    a. North Central
    b. Northern Kentucky
    c. Bluegrass District
    d. Western Kentucky

Fee is $15.90 (sales tax included) for Kentucky residents and $15.00 for out-of-state residents. Please make checks payable to: "**Kentucky State Treasurer**." Submit your check and answer sheet to:

KENTUCKY BOARD OF PHARMACY
23 MILLCREEK PARK
FRANKFORT, KY 40601-9230

Successful completion of at least 80% of questions will result in **0.2 CEU's**.

HIV INFECTION: CONTINUING EDUCATION FOR HEALTH-CARE PROVIDERS IN 2004

1.	A	B	C	D	6.	A	B	C	D
2.	A	B	C	D	7.	A	B	C	D
3.	A	B	C	D	8.	A	B	C	D
4.	A	B	C	D	9.	A	B	C	D
5.	A	B	C	D	10.	A	B	C	D

NAME:_____

ADDRESS:_____

_____

KY LICENSE NUMBER:_____

PROFESSION: PHARMACY/PODIATRY (please circle)

COMMENTS:_____

_____

This lesson was approved by the Kentucky Cabinet for Health Services (CHS) as a provider of HIV/AIDS continuing education in Kentucky and assigned number **CHS 0306-1045-S**

Please note, the above HIV/AIDS program is not an ACPE accredited program.

The Kentucky Omnibus AIDS Act of 1990 mandates AIDS education for health-care professionals. All health-care professionals applying for initial licensure must comply with the statutory requirement for one (1) hour (pharmacists) and two (2) hours (podiatrists) of HIV/AIDS education approved by the Cabinet for Health Services.

CHS, not the Board of Pharmacy or Board of Podiatry is responsible for approval of HIV/AIDS education curricula and courses. CHS does not review individual courses that applicants have already completed. For further information, please contact the HIV/AIDS Branch at (502)-564-6539.

Kentucky community-based organizations (CBOs)

Community-based organizations provide a variety of resources for both those infected and affected by HIV disease. Following is our current list of CBOs:

Eastern area

Agency name	Mailing address	Tel/fax/e-mail	Description
Tri-State AIDS Task Force	945 4th Avenue, Suite 119 Huntington WV 25701 Att: Melissa Browning	Tel: 304-522-4357 888-299-2437 Fax: 604-525-2061 E-mail: tsatf@aol.com	

Lexington area

Agency name	Mailing address	Tel/fax/e-mail	Description
AIDS Volunteers (AVOL)	PO Box 431 Lexington KY 40585 Att: Kathy Cox	Tel: 859-278-7494 Fax: 859-278-9667 E-mail: avol@juno.com	Provides financial assistance, support and legal referrals. Strong prevention focus
Micro-City Government	522 Patterson St. Lexington KY 40508 Att: Sean Edwards	Tel: 859-255-5897 Fax: 859-253-0958 E-mail:	Education and prevention for inner city youth. Condom distribution service.
Robert H. Williams Cultural Center	644 Georgetown Street Lexington KY 40508 Att: Carolyn Bell	Tel: 859-255-5068 Fax: 859-255-5068 (call 1st) E-mail:	Intervention programs for African-American population in the Greater Bluegrass

Louisville area

Agency name	Mailing address	Tel/fax/e-mail	Description
AIDS Interfaith Ministries (AIM)	850 Barret Ave., #305A Louisville KY 40204 Att: Stacy Jaudon	Tel: 502-574-6086 Fax: 502-574-5244 E-mail: sjaudon@aol.com	Pastoral counseling and Care Teams for those who are affected by HIV/AIDS.
AIDS Services Center Coalition & Louisville AIDS Walk	810 Barret Ave, #270 Louisville KY 40204	Tel: 502-574-5490/5947 Fax: 502-574-5497 E-mail: ascctrc@aol.com	Coalition of agencies that provide direct services to persons living with HIV/AIDS.
American Red Cross	510 E. Chestnut St. Louisville KY 40202 Att: Marilyn Peter	Tel: 502-589-4460 Fax: 502-561-3617 E-mail:	Educational programs for the workplace. Brochures and films for the community. Monthly education programs, HIV/AIDS instructor class for African-Americans, and AIDS education certification for health professionals.
Community Health Trust	PO Box 4277 Louisville KY 40204 Att: Stephen Stanton	Tel: 502-574-5496 Fax: 502-574-5497 E-mail: cht@ka.net	Serves prevention, education and healthcare needs of gay men, lesbians and all people with HIV.

Kentucky community-based organizations (CBOs)

Louisville area (continued)

Agency name	Mailing address	Tel/fax/e-mail	Description
HIV/AIDS Legal Project	810 Barret Ave, #277 Louisville KY 40204 Att: Jeff Been	Tel: 502-574-8199 Fax: 502-574-5244 E-mail:	Free legal services for HIV-infected persons at or below 125% poverty level. Legal education on issues relating to HIV/AIDS.
House of Ruth	607 E. St. Catherine St Louisville KY 40203 Att: Sr. Julie Driscoll	Tel: 502-587-5080 Fax: 502-587-5009 E-mail: housofruth@aol.com	Association of caring persons for women, children and families affected by HIV.
KALA (Kentucky AIDS Life Alliance)	850 Barret Ave, # 304J Louisville KY 40232-2144 Att: Daniel Coe	Tel: 502-969-0336 Fax: 502-574-8484 E-mail: kala2000@juno.com	Support & empowerment group for people living with HIV/AIDS and those directly affected by the disease.
Kentucky Hemophilia Foundation	982 Eastern Parkway Louisville KY 40217-1566 Att: Ursela Lacer	Tel: 502-634-8161 Fax: 502-634-9995 E-mail: kyhemo@bellsouth.net	Education, advocacy & support services for individuals and families affected by inherited bleeding disorders and complications such as HIV/AIDS.
Louisville-Jefferson County Minority AIDS Council (LJCMAC)	233 West Broadway, #120 Louisville KY 40202 Att: Stephanie Benson	Tel: 502-585-4733 Fax: 502-585-9648 E-mail: ljcmac@iglou.com	Promotes AIDS prevention and education through outreach programs directed towards KY's minority population.
LifePerserver Educational Services, Inc.	1939 Goldsmith Lane, #18 Louisville KY 40218-2006 Att: Mark Saunders	Tel: 502-458-9319 Fax: 502-458-9378 E-mail: lpesi@aol.com	HIV prevention and education. Reaches African-American community through its community leaders.
SABSA (Sisters and Brothers Surviving AIDS)	PO Box 505 Louisville KY 40201	Tel: 502-588-5704 (voice mail) Fax: E-mail:	
Volunteers of America	1321 South Preston Louisville KY 40208 Att: Tina Haley	Tel: 502-634-5584 Fax: 502-634-5554 E-mail: thaley@mepsinet.net	Promotes HIV prevention and education through outreach programs. Programs target African-American women, youth, men who have sex with men, gay men of color and injectable drug users.
Watson Memorial Baptist Church	c/o 3006 Summerfield Dr. Louisville KY 40220 Att: Libby Burks-Weathers	Tel: 502-499-7346 Fax: E-mail:	Provides education and outreach to local community. Targets African-Americans and youth.

Kentucky community-based organizations (CBOs)

Louisville area (continued)

WINGS Clinic	Dept. of Family & Community Medicine 530 South Jackson Street Louisville KY 40292 Att:: Dr Karen Krigger & Dr Anna Huang	Tel: 502-852-5203 Fax: 502-852-0982 E-mail: adperm01@med.louisville.edu	This clinic project services HIV+ women and children, providing primary and infectious disease care adult and pediatric nutrition services, adult support groups, social services, legal services, family & mental health counseling, as well as liaisons to community services.

Northern area

Agency name	Mailing address	Tel/fax/e-mail	Description
AIDS Volunteers of Northern KY	314 War Horse Place Crestview KY 41017 Att: Michael Connley	Tel: 859-331-4719 (home) 513-287-3720 (work) 513-483-5757 (voice mail) Fax: E-mail: mconnley@cinergy.com	Support groups, emergency financial assistance, monthly dinner/social, respite care healing weekends, transportation, World AIDS Day Coordination.
No. KY AIDS Consortium	610 Medical Village Drive Edgewood KY 41017 Att: Sue Beck RN, Chair	Tel: 859-341-4264 Fax: 859-578-3689 E-mail: ckunkel-mains@nkyhealth.org	Advisory & advocacy coalition of professionals and clients that meets the needs of HIV+ individuals & educates the community.

Western area

Agency name	Mailing address	Tel/fax/e-mail	Description
HIV/AIDS Taskforce	600 Locust Street Owensboro KY 42301 Att: Rita Brothers	Tel: 270-683-1545 Fax: E-mail:	Catholic pastoral center that teaches about the Church's doctrines regarding persons infected with HIV/AIDS. Promotes a non-discriminatory, inclusive policy.
KIPWAC	1501 Broadway Annex #2 Paducah KY 42001 Att: Hazel Jerrell	Tel: 888-575-4871 270-462-3828 Fax: 270-575-4863 E-mail: hjerrell@brtc.net	Confidential support groups for HIV+ people and others. Promotes self-empowerment for people with HIV/AIDS. Governed by a board of directors, more than half of whom are HIV+.

Kentucky community-based organizations (CBOs)

Western area

Agency name	Mailing address	Tel/fax/e-mail	Description
Heartland Clinic & Heartland CARES	3025 Clay Street Paducah KY 42001 Att: Krista Wood	Tel: 270-444-8183 Fax: 270-444-8147 E-mail: hci@klh.net	Clinic: Comprehensive primary care services for those infected with HIV; mental health services; substance abuse counseling; nutritional assessment & counseling; drug access program & compassionate use; massage therapy; dental services; exercise program; HIV antibody testing; and testing and treatment for STD's. Support services: HOPWA Supportive Housing; emergency assistance; support groups; case mgmt.; outreach/prevention/education; financial counseling; and specialty, agency and medical referrals.
Matthew 25 AIDS Services	Paff Haus 435 First Street Henderson KY 42420 Att: Cyndee Burton	Tel: 270-826-0200 Fax: 270-827-7466 E-mail: lncburton@dynasty.net	Provides friendship and prayers for those infected/affected by HIV/AIDS through support group, education for self care and empowerment, buddy program, spiritual support, and important links in the community. Also provides education to the community by an Annual AIDS Awareness Walk every October; Coordinators of World AIDS Day Services and community involvement each Dec. 1. Approved HIV/AIDS Course and Speakers Bureau.

OVERVIEW OF SERVICES AVAILABLE THROUGH KENTUCKY'S RYAN WHITE AND STATE-FUNDED SERVICES PROGRAMS

Kentucky HIV Care Coordinator Program (KHCCP)

Purpose: The intent of the KHCCP is to facilitate the provision of quality care and services to HIV infected individuals and their families in a timely and consistent manner across a continuum of care. The program provides Care Coordinators in six regional sites through arrangements with 4 local health departments, (Barren River, Cumberland Valley, Lexington, and Northern Kentucky) and two non-profit agencies (Louisville and Purchase), to aid the client in identifying and accessing needed services. These regional sites allow for statewide coverage, and better local access to these services. KHCCP also acts as an umbrella program for other client assistance programs such as the Kentucky Health Insurance Assistance, Outpatient Health Care and Support Services, and the State Support Services Programs. ***(Continuation of all programs is contingent upon continued state and federal funding.)***

Goals of KHCCP:

- To optimize the client's self-care capabilities by empowering him/her to direct his/her own life decisions.
- To identify the extent of the client's informal support systems.
- To assist the client in locating and accessing existing services in areas including entitlement benefits (Medicaid and/or Social Security Disability Services), medical care, housing, counseling, transportation, legal and nutrition services.
- To identify and establish a referral system with area health care and social service providers and community-based HIV organizations, and HIV counseling and testing sites.
- To ensure that duplication of services by formal and informal support systems does not occur.
- To provide the client with educational information regarding disease transmission and maintenance of a healthy lifestyle, and encourage and reinforce good health habits and secondary prevention methods over the course of case management.
- To identify and document patterns of service needs and advocate for effective policies and resource development.
- To facilitate the initial and on-going education of health care and social service providers to the issues surrounding HIV disease.
- To ensure that program funding is appropriately used to meet the documented needs of HIV+ persons throughout the State in a manner that coordinates funding streams and makes use of existing community resources and services.

Basic Eligibility Criteria for Financial Assistance Programs:

- Household Income - 300% of federal poverty level, or less.
- Household Resources - cash assets of less than $10,000.
- Client Residency - must be a resident of Kentucky.
- Medical Documentation - HIV+ status must be confirmed with appropriate documentation. (For KADAP participation, medical documentation must also include CD4+ T cell count and viral load.)
- Lack of Other Third Party Payer - must be ineligible for assistance from other third party payers for the assistance being requested.

FINANCIAL ASSISTANCE PROGRAMS

Kentucky AIDS Drug Assistance Program (KADAP) - This program assists low-income, eligible Kentuckians with the purchase of AIDS-related medications prescribed for FDA-approved indications. Drugs currently covered are: abacavir (Ziagen); acyclovir (Zovirax); amprenavir (Agenerase); AZT (Retrovir); ciprofloxacin (Cipro); clarithromycin (Biaxin); clotrimazole (Mycelex); dapsone; ddC (HIVID); ddI (Videx); delavirdine (Rescriptor); efavirenz (Sustiva); fluconazole (Diflucan); hydrea (Hydroxyurea); indinavir (Crixivan); ketoconazole (Nizoral); lamivudine (3TC, Epivir); lamivudine/zidovudine (Combivir); megestrol acetate (Megace); nelfinavir (Viracept); nevirapine (Viramune); nystatin (Mycostatin); pentamidine (NebuPent); rifabutin (Mycobutin); ritonavir (Norvir); saquinavir (Invirase & Fortovase); stavudine (Zerit, d4T); trimethoprim and sulfamethoxazole (Bactrim and Septra); and zithromax (Azithromycin). Once approved, eligible applicants receive formulary medications through a mail-order pharmacy service provided by U of L Outpatient Pharmacy. **NOTE: Effective 2/1/00, a waiting list was established for this program.**

Kentucky Health Insurance Assistance Program (KHIAP) - provides payments for the continuation of health insurance benefits for eligible individuals and their families who are at risk of losing their employment-related or private-pay health insurance because of HIV disease.

Kentucky Outpatient Health Care and Support Services Programs - provide assistance for eligible individuals with a wide range of community-based medical and non-medical support services, such as, but not limited to, physical and mental health care, housing, nutrition, and transportation services. From the list of eligible services, ***priority services*** are identified during each funding period, based on such factors as client and Care Coordinator input, needs assessment survey results, resource inventories, client satisfaction surveys, and funding limitations.

Care Coordinator Programs by region (including the Area Development Districts and Counties covered by the region):

Barren River Region - based in Barren River Dist. Health Dept., PO Box 1157, Bowling Green, KY 42101-1157
(270) 781-8039 (telephone); (800) 599-4448 (for client use only); (270) 796-8946 (fax)
Area Development Districts Covered: Barren River, Green River, and Lincoln Trail
Counties Covered:

Allen	Daviess	Hardin	Logan	Metcalfe	Simpson	Webster
Barren	Edmonson	Hart	McLean	Monroe	Union	
Breckinridge	Grayson	Henderson	Marion	Nelson	Warren	
Butler	Hancock	Larue	Meade	Ohio	Washington	

Cumberland Valley Region - based in Cumberland Valley Dist. Health Dept., 408 N Main St Suite 5, London, KY 40741
(606) 864-3776 (telephone); (888) 425-7282 (for client use only); (606) 864-3732 (fax)
Area Development Districts Covered: Lake Cumberland, Cumberland Valley, Kentucky River, and Big Sandy
Counties Covered:

Adair	Clinton	Jackson	Lee	McCreary	Rockcastle	Wolfe
Bell	Cumberland	Johnson	Leslie	Owsley	Russell	
Breathitt	Floyd	Knott	Letcher	Perry	Taylor	
Casey	Green	Knox	Magoffin	Pike	Wayne	
Clay	Harlan	Laurel	Martin	Pulaski	Whitley	

Lexington Region - based in Lexington-Fayette Co. Health Dept., 650 Newtown Pike, Lexington, KY 40508-1197
(859) 288-2437; (telephone); (877) 606-2437 (tel – for client use only); (859) 288-7512 (fax)
Area Development Districts Covered: Bluegrass, Buffalo Trace, FIVCO, and Gateway
Counties Covered:

Anderson	Bracken	Fayette	Harrison	Madison	Morgan	Scott
Bath	Carter	Fleming	Jessamine	Mason	Nicholas	Woodford
Bourbon	Clark	Franklin	Lawrence	Menifee	Powell	
Boyd	Elliott	Garrard	Lewis	Mercer	Robertson	
Boyle	Estill	Greenup	Lincoln	Montgomery	Rowan	

Louisville Region - based in Volunteers of America of KY (VOA), 850 Barret Ave., Suite 302, Louisville, KY 40204
(502) 574-0161 (telephone); (502) 574-8484 (fax)
Area Development District Covered: KIPDA
Counties Covered:

Bullitt	Henry	Jefferson	Oldham	Shelby	Spencer	Trimble

Northern Kentucky Region - based in Northern KY Dist. Health Dept., 610 Medical Village Drive, Edgewood, KY 41017
(859) 341-4264 (telephone); (859) 578-3689 (fax)
Area Development District Covered: Northern Kentucky
Counties Covered:

Boone	Carroll	Gallatin	Grant	Kenton	Owen	Pendleton
Campbell						

Purchase Region - based in Pennyrile Allied Community Services (PACS), PO Box 1102, Princeton, KY 42445
(800) 522-8289 (telephone); (270) 365-5726 (fax)
Area Development Districts Covered: Pennyrile and Purchase
Counties Covered:

Ballard	Carlisle	Fulton	Hopkins	McCracken	Todd
Caldwell	Christian	Graves	Livingston	Marshall	Trigg